

## REMARKS

Claims 1-9, 12-18, 20-22 and 25-30 are pending.

### RESPONSE TO CLAIM REJECTIONS UNDER 35 USC § 112¶2

Claims 1-5, 7, 12-18, 20-22 and 25-30 are rejected for failing to comply with the written description requirement; the Examiner asserts that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner rejects to the following claim language: “wherein said composition provides extended release of said antineoplastic agent into said anatomic area; for a period of at least seven days, the rate of release of the antineoplastic agent is approximately constant.”

The Applicants respectfully assert that support for the rejected claim language can be found on page 6, lines 16-24.

Accordingly, the Applicants respectfully request withdrawal of the 35 USC § 112¶2 based rejection of the pending claims.

### RESPONSE TO CLAIM REJECTIONS UNDER 35 USC § 103(a)

Claims 1-5, 7, 12-18, 20-22 and 25-30 have been rejected as being unpatentable over US Patent No. 5,651,986 (‘986) in view of US Patent No. 6,166,173 (‘173). The Examiner cites the ‘986 patent for disclosing a method of treating brain cancer (a central nervous system neoplasm) of a patient comprising instilling into an anatomic area of a patient affected by brain cancer a therapeutically effective amount of a composition comprising a biocompatible polymer and an antineoplastic agent. The Examiner states that the ‘986 patent fails to disclose the claimed polymers. The Examiner asserts that the deficiencies of the ‘986 patent are cured by the ‘173 patent. Specifically, the Examiner asserts that the ‘173 patent has all of the structural limitations of the presently claimed biocompatible polymers. The Applicants respectfully traverse.

Assuming *arguendo* that the Examiner has made a *prima facie* showing of obviousness, the Applicants respectfully assert that the unexpectedly improved benefits of the claimed

methods negate such a showing because an “assumed similarity must give way to evidence that [such an] assumption is erroneous.” *In re Papesch*, 315 F.2d 381, 391 (CCPA 1979). The Applicants direct the Examiner’s attention to page 94, lines 18-23, of the instant application wherein the method of using the PCPP-SA implants of the ‘986 patent is discussed. As noted therein, the ‘986 method utilizes implants which release their antineoplastic agents in a biphasic pattern (i.e., with an initial burst of drug followed by a much slower release of drug over months). Importantly, the ‘986 method resulted in sporadic toxicity among the animals after implantation (due to the initial burst of drug) and therefore such a method is clearly suboptimal for clinical application. Based on the results of the ‘986 method, Applicants respectfully assert that one of skill in the art would have expected to see a similar initial burst of drug release with the compositions employed in the claimed methods. However, as described on page 94, lines 24-27, the use of the claimed compositions unexpectedly resulted in a constant *in vitro* rate of release (i.e. no initial burst). Further, contrary to the Examiner’s assertion, the unexpected *in vitro* constant rate of release is not simply attorney argument; the experimental results of the *in vitro* experiments are in fact disclosed in the instant application (see Figure 1). Therefore, having not responded to the disclosed unexpected results of the claimed methods, Applicants respectfully assert that the Examiner has not properly set forth a rejection under § 103.

In addition, it is improper, in determining whether a person of ordinary skill in the art would have been led to this combination of references, to simply use “that which the inventor taught against its teacher.” *In re Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002), citing *W.L. Gore & Assocs.*, 837 F.2d 469, 473 (Fed. Cir. 1988)(“[t]here must be reason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicant’s disclosure”); *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 381 F.3d 1371 (Fed. Cir. 2004)(“the suggestion to combine references must not be derived by hindsight from knowledge of the invention itself.”) Specifically, the Examiner may not use the Applicants disclosure of the use of the certain polymeric compositions in methods for treating central nervous system neoplasms as a blueprint to reconstruct the claimed invention from the isolated pieces of cited prior art, as this contravenes the statutory mandate of § 103 which requires judging obviousness at the time the invention was made. The Applicants respectfully assert that absent the teaching of the instant invention, the ‘986 patent can not be combined with the ‘173 patent to render obvious the claimed methods. Specifically, given that one of skill in the art would have expected the claimed

compositions to have an initial burst based on the '986 patent, the Applicants respectfully assert that absent the teaching of the instant application one of skill in the art would not have been motivated to combine the cited references in an attempt to avoid or minimize the initial burst of drug release.

Accordingly, the Applicants respectfully request the withdrawal of the claim rejections based on 35 U.S.C. § 103(a).

### **FEES**

The Applicants believe that all fees required in connection with the filing of this Response have been provided. Nevertheless, the Commissioner is hereby authorized to charge any fees due in connection with the filing of this Response to our Deposit Account, No. **06-1448**, Reference **GPT-030.01**.

### **CONCLUSION**

The Applicants believe that the pending claims are in condition for allowance. If a telephone conversation would expedite prosecution of the above-identified application, the Examiner is urged to contact the undersigned.

Respectfully submitted,  
FOLEY HOAG LLP

By: /Jacob I. Wasserman/

155 Seaport Boulevard  
Boston, MA 02210

Telephone: (617) 832-1000  
Telecopier: (617) 832-7000

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Jacob I. Wasserman, Ph.D.  
Reg. No. 56,929  
Attorney for Applicants